

REMARKS

This is a full and timely response to the non-final Official Action mailed May 11, 2010 (the "Office Action" or "Action"). Reconsideration of the application in light of the above amendments and the following remarks is respectfully requested.

Claim Status:

Under the imposition of a previous provisional restriction requirement, claims 33-42 have been withdrawn from consideration. Of these, claim 34 has been cancelled previously without prejudice or disclaimer. Additionally, claim 42 has been amended. Applicant will be entitled to rejoinder of claims 33 and 35-42 upon allowance of independent claims 1, 20 and 28. MPEP § 821.04.

By the forgoing amendment, claims 1, 20, 28, 29, 31, and 32 have been amended. Of these original claims, claims 21 and 30 were cancelled previously without prejudice or disclaimer. Thus, claims 1-20, 22-29, 31 and 32 are currently pending for further action.

35 U.S.C. § 112, second paragraph:

In the recent Office Action, claims 28, 29, 31, and 32 were rejected under 35 U.S.C. § 112, second paragraph. These claims have been carefully reviewed in light of the Examiner's comments.

While Applicant does not necessarily agree that any of these claims were indefinite as filed, the indicated claims have been amended herein to address the issues raised by the Examiner under 35 U.S.C. § 112, second paragraph. Following this amendment, all the remaining claims are believed to be in compliance with 35 U.S.C. § 112 and notice to that effect is respectfully requested.

Objection to Specification:

In the outstanding Office Action, the Examiner objected to the specification because of an informality. Specifically, the written description allegedly only implicitly or inherently sets forth the corresponding structure, material, or acts that perform the function as claimed in claim 29. However, Applicant respectfully disagrees. The Applicant's specification clearly sets forth an eye-position detector which can, for example, include an image pick-up device. (Applicant's Specification, para. 23). Other non-exclusive examples may further be detailed in the specification. Therefore, the objection to the specification should be reconsidered and withdrawn.

Prior Art:

1. In the recent Office Action, claims 1, 2, 4, 9, and 16 were rejected under 35 U.S.C. § 102(a) or (e) as being anticipated by U.S. Patent Application Publication No. 2004/0267214 to Kerssies (hereinafter Kerssies). For at least the following reasons, this rejection should be reconsidered and withdrawn.

Claim 1:

Claim 1 recites:

An ophthalmic apparatus comprising:
an eye-positioning device comprising:
an electronic feedback device configured to provide information to a subject who is moving an eye from a current position to a desired position relative to the eye positioning device; and
an applicator for dispensing the fluid into the eye conditionally upon positioning of the eye in the desired position.
(Emphasis added).

Support for the amendment to claim 1 can be found in Applicant's originally filed specification at, for example, paragraph [0061].

In contrast, Kerssies does not teach or suggest "[a]n ophthalmic apparatus comprising: . . . an electronic feedback device." (Claim 1). The Office Action argues that "Kerssies teaches an ophthalmic apparatus comprising: . . . a feedback device . . . configured to provide information to a subject who is moving an eye from a current position to a desired position relative to the eye positioning device." (Action, p. 6). At best, however, Kerssies teaches a base portion having "on its side directed towards the eye, an entirely or partially reflecting and/or colour-discriminating surface." (Kerssies, para. [0013]). Clearly, a reflecting surface is not an electronic feedback device.

In contrast, claim 1 recites "[a]n ophthalmic apparatus comprising: . . . an *electronic* feedback device." (Claim 1) (emphasis added). This subject matter is clearly not taught or suggested by Kerssies.

Respectfully, to anticipate a claim, a reference must teach each and every element of the claim, and "the identical invention must be shown *in as complete detail as contained in the ... claim.*" MPEP 2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987) and *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989) (emphasis added). Moreover, "[t]he prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements 'arranged as in the claim.'" *NetMoneyIn v. Verisign*, (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542 (Fed. Cir. 1983)).

In the present case, Kerssies clearly does not disclose the claimed invention with each and every claimed element in the same amount of detail or as arranged in the claim.

Consequently, because Kerssies clearly fails to satisfy the requirements for anticipating claim 1, the rejection of claim 1 and its dependent claims should be reconsidered and withdrawn.

Additionally, various dependent claims of the application recite subject matter that is further patentable over the cited prior art. Specific, non-exclusive examples follow.

Claim 9

Claim 9 recites:

The apparatus of claim 1, wherein the applicator comprises:
a frame for wearing on the head of the subject; and
a fluid dispenser supported by the frame proximate the eye of the
subject, the fluid dispenser configured to dispense fluid into the eye.
(Emphasis added).

In contrast, Kerssies does not teach or suggest an “applicator compris[ing]: a frame for ***wearing on the head*** of the subject.” (Claim 9) (emphasis added).

It should first be noted that in rejecting claim 9, the Office Action fails to cite a reference within Kerssies that teaches a frame wearing on the head of the subject. (See Action, p. 7). It is incumbent upon the Examiner to identify where in the reference each element may be found. *Ex parte Levy*, 17 U.S.P.Q.2d 1461 (BPAI 1990). Consequently, when the Examiner fails to identify a claimed element, the Examiner has failed to establish a *prima facie* case of anticipation.

Despite this, however, Kerssies at best teaches that:

[the shape of the positioning member] is preferably circular or oval, whereby a good universal fit of the device ***near the eye*** of the user is obtained. The ***positioning member 3*** is to the side of the eye, furthermore, is provided preferably with rounded angles and possibly a thickening, and is finished in such a manner that ***it can be held fast against the head*** without irritation.” (Kerssies, para. [0050]) (emphasis added).

Therefore, nowhere in Kerssies is it taught or suggested that a frame is worn on the head. Instead, Kerssies teaches that the device is to be placed in proximity to the eye and “held fast against the head” and not worn on the head at all. (*Id.*).

In contrast, claim 9 recites an “applicator compris[ing]: a frame for wearing on the head of the subject.” (Claim 9). This is clearly not taught in Kerssies.

Again, to anticipate a claim, a reference must teach each and every element of the claim, and “the identical invention must be shown *in as complete detail as contained in the ... claim.*” MPEP 2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 2 USPQ2d 1051 (Fed. Cir. 1987) and *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989) (emphasis added). Moreover, “[t]he prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *NetMoneyIn v. Verisign*, (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542 (Fed. Cir. 1983)).

In the present case, Kerssies clearly does not disclose the claimed invention with each and every claimed element in the same amount of detail or as arranged in the claim. Consequently, because Kerssies clearly fails to satisfy the requirements for anticipating claim 9, the rejection of claim 9 and its dependent claims should be reconsidered and withdrawn.

2. In the recent Office Action, claims 20 and 23 were rejected under 35 U.S.C. § 102(a) or (e) as being anticipated by U.S. Patent No. 6,945,650 to Beverly (hereinafter Beverly). For at least the following reasons, this rejection should be reconsidered and withdrawn.

Claim 20:

Claim 20 recites:

An ophthalmic apparatus, comprising:
a dispensing apparatus for dispensing fluid into an eye of a subject;
an eye-position detector for detecting the current position of the eye
relative to the dispensing apparatus; and
a feedback device for receiving information from the eye-position
detector corresponding to the position of the eye,
***wherein the feedback device provides feedback information to the
subject that assists the subject in moving the eye*** from the current position to
a predetermined position relative to the dispensing apparatus for administering
the fluid to the eye.

(Emphasis added).

Support for the amendment to claim 20 can be found in Applicant's originally filed specification at, for example, paragraph [0024].

In contrast, Beverly does not teach or suggest "[a]n ophthalmic apparatus, comprising: . . . a feedback device for receiving information from the eye-position detector, . . . wherein the feedback device provides feedback information to the subject that assists the subject in moving the eye." (Claim 20). It should be first noted that the previous final office action of February 4, 2010 conceded that "Beverly does not expressly teach that the feedback device provides information to the subject that assists the subject in moving the eye from the current position to a predetermined position relative to the dispensing apparatus." (Final Office Action of Feb. 4, 2010, p. 5).

Indeed, nowhere in Beverly is it taught or suggested that a subject receives instructions from a feedback device to change his or her eye position relative to the apparatus. In fact, Beverly teaches that the "[h]eads-up display 24 comprises a polar array 82 of light-emitting diodes 84 . . . ***for providing an X-Y alignment instruction to the operator***. (Beverly, col. 7, ll. 54-67) (emphasis added). Additionally, Beverly teaches that "***the operator*** is being instructed ***to move the instrument*** lower and to the left for X-Y alignment, and closer to the

and closer to the eye for Z alignment.” (*Id.* at col. 8, ll. 28-53). Clearly, Beverly teaches that another person, namely the operator, is instructed to move the instrument.

Additionally, the Office Action suggests that “Beverly’s device is capable of providing information that helps the subject in moving the eye.” (Action, p. 8). However, Beverly teaches that a heads-up display is provided to the operator and comprises “LEDs 84 in polar array 82 . . . whereby *the LEDs are selectively illuminated depending upon the X-Y alignment status* of the instrument relative to the eye.” (Beverly, col. 7, ll. 53-67) (emphasis added). Additionally, Beverly teaches that “*an LED 84 is illuminated corresponding to an appropriate directional pointer* instructing the operator of the direction to move the instrument to align optical axis 14 with corneal vertex V.” (*Id.* at col. 8, ll. 1-27) (emphasis added). Therefore, it is clear that if the subject in Beverly were to align his or her own eye using the heads up display as suggested in Beverly, the subject would be forever checking to see if the adjustments to the eye were correct per the heads-up display and subsequently attempting to place that same eye (which is being aligned) in the correct position, just to have to look to see on the heads-up display yet again if the position is correct.

Simply put, the proposed modification of Beverly would render Beverly unsatisfactory for its intended purpose. “If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984).” M.P.E.P. § 2143.01. Therefore, Beverly fails to teach or suggest the recitations found in claim 20.

Respectfully, to anticipate a claim, a reference must teach each and every element of the claim, and “the identical invention must be shown *in as complete detail as contained in the ... claim.*” MPEP 2131 citing *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d

628, 2 USPQ2d 1051 (Fed. Cir. 1987) and *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989) (emphasis added). Moreover, “[t]he prior art reference—in order to anticipate under 35 U.S.C. § 102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those elements ‘arranged as in the claim.’” *NetMoneyIn v. Verisign*, (Fed. Cir. 2008) (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542 (Fed. Cir. 1983)).

In the present case, Beverly clearly does not disclose the claimed invention with each and every claimed element in the same amount of detail or as arranged in the claim. Consequently, because Beverly clearly fails to satisfy the requirements for anticipating claim 20, the rejection of claim 20 and its dependent claims should be reconsidered and withdrawn.

3. In the recent Office Action, claims 1, 2, 4-6, 8, 9, 16, 28, and 31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,945,650 to Beverly (hereinafter Beverly) in view of U.S. Patent Application Publication No. 2004/0267214 to Kerssies (hereinafter Kerssies). For at least the following reasons, this rejection should be reconsidered and withdrawn.

Claim 1:

Claim 1 recites:

An ophthalmic apparatus comprising:
an eye-positioning device comprising:
an electronic feedback device configured to provide information to a subject who is moving an eye from a current position to a desired position relative to the eye positioning device; and
an applicator for dispensing the fluid into the eye conditionally upon positioning of the eye in the desired position.
(Emphasis added).

Support for the amendment to claim 1 can be found in Applicant's originally filed specification at, for example, paragraph [0061].

In contrast, Kerssies and Beverly in any combination do not teach or suggest "[a]n ophthalmic apparatus comprising: . . . an electronic feedback device configured to provide information to a subject." (Claim 1).

The Office Action concedes first that "Beverly does not teach that the feedback device is *configured* to provide information *to a subject*." (Action, p. 10). In order to overcome this deficiency the Office Action relies on Kerssies and argues that "Kerssies teaches an ophthalmic device that provides feedback to the subject so that the subject can choose to move the eye to a desired position so that eye drops will be dispensed onto the iris." (Action, p. 10). At best, however, Kerssies teaches a base portion having "on its side directed towards the eye, an entirely or partially reflecting and/or colour-discriminating surface." (Kerssies, para. [0013]). Clearly, a reflective surface is not an electronic feedback device.

In contrast, claim 1 recites "[a]n ophthalmic apparatus comprising: . . . an electronic feedback device." (Claim 1). This subject matter is clearly not taught or suggested by Kerssies.

The Supreme Court has addressed the issue of obviousness in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007). The Court stated that the *Graham v. John Deere Co. of Kansas City*, 383, U.S. 1 (1966), factors still control an obviousness inquiry. Under the analysis required by *Graham* to support a rejection under § 103, the scope and content of the prior art must first be determined, followed by an assessment of the differences between the prior art and the claim at issue in view of the ordinary skill in the art. In the present case, the scope and content of the prior art, as evidenced by Beverly and Kerssies, did not include the claimed

subject matter, particularly an ophthalmic apparatus comprising an electronic feedback device.

The differences between the cited prior art and the indicated claims are significant because recitation of claim 1 allows a user of the apparatus to operate the apparatus himself and to receive feedback from the apparatus as to how to position the eye for proper administration of the liquid. Thus, the claimed subject matter provides features and advantages not known or available in the cited prior art. Consequently, the cited prior art will not support a rejection of claim 1 under 35 U.S.C. § 103 and *Graham*.

Claim 28

Claim 28 recites:

An ophthalmic apparatus for administering a liquid to an eye of a subject, comprising:
means for detecting the position of the eye;
means for receiving feedback information from the means for detecting the position of the eye corresponding to the position of the eye,
wherein the means for receiving feedback information provides feedback information to the subject that assists the subject in moving the eye from the current position to a predetermined position relative to the ophthalmic apparatus; and
means for dispensing the liquid into the eye only when the eye is in the predetermined position.

(Emphasis added).

Support for the amendment to claim 28 can be found in Applicant's originally filed specification at, for example, paragraph [0024].

In contrast, Beverly does not teach or suggest "[a]n ophthalmic apparatus . . . comprising: . . . means for receiving feedback information, . . . wherein the means for receiving feedback information provides feedback information to the subject that assists the subject in moving the eye from the current position to a predetermined position relative to the

ophthalmic apparatus.” (Claim 28). It should be first noted that the previous final office action of February 4, 2010 conceded that “Beverly does not expressly teach that the feedback device provides information to the subject that assists the subject in moving the eye from the current position to a predetermined position relative to the dispensing apparatus.” (Final Office Action of Feb. 4, 2010, p. 5). Indeed, nowhere in Beverly is it taught or suggested that a subject receives instructions from a feedback device to change his or her eye position relative to the apparatus. In fact, Beverly teaches that the “[h]eads-up display 24 comprises a polar array 82 of light-emitting diodes 84 . . . *for providing an X-Y alignment instruction to the operator*. (Beverly, col. 7, ll. 54-67) (emphasis added). Additionally, Beverly teaches that “*the operator* is being instructed *to move the instrument* lower and to the left for X-Y alignment, and closer to the eye for Z alignment.” (*Id.* at col. 8, ll. 28-53). Clearly, Beverly teaches that another person, namely the operator, is instructed to move the instrument.

Additionally, the Office Action suggests that “Beverly teaches an ophthalmic apparatus, comprising: . . . a feedback device/means (24) for receiving information from the detecting means corresponding to the position of the eye.” (Action, p. 11). However, Beverly teaches that a heads-up display is provided to the operator and comprises “LEDs 84 in polar array 82 . . . whereby *the LEDs are selectively illuminated depending upon the X-Y alignment status* of the instrument relative to the eye.” (Beverly, col. 7, ll. 53-67) (emphasis added). Additionally, Beverly teaches that “*an LED 84 is illuminated corresponding to an appropriate directional pointer* instructing the *operator* of the direction to move the instrument to align optical axis 14 with corneal vertex V.” (*Id.* at col. 8, ll. 1-27) (emphasis added). Therefore, it is clear that if the subject in Beverly were to align his or her own eye using the heads up display as suggested in Beverly, the subject would be forever checking to see if the adjustments to the eye were correct per the heads-up display and subsequently

attempting to place that same eye (which is being aligned) in the correct position, just to have to look to see on the heads-up display yet again if the position is correct. Simply put, the proposed modification of Beverly would render Beverly unsatisfactory for its intended purpose. "If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)." M.P.E.P. § 2143.01. Therefore, Beverly fails to teach or suggest the recitations found in claim 28.

Again, the Court stated that the *Graham v. John Deere Co. of Kansas City*, 383, U.S. 1 (1966), factors still control an obviousness inquiry. Under the analysis required by *Graham* to support a rejection under § 103, the scope and content of the prior art must first be determined, followed by an assessment of the differences between the prior art and the claim at issue in view of the ordinary skill in the art. In the present case, the scope and content of the prior art, as evidenced by Beverly and Kerssies, did not include the claimed subject matter, particularly an ophthalmic apparatus comprising a means for receiving feedback information wherein the means for receiving feedback information provides feedback information to the subject that assists the subject in moving the eye from the current position to a predetermined position relative to the ophthalmic apparatus.

The differences between the cited prior art and the indicated claims are significant because recitation of claim 28 allows a user of the apparatus to operate the apparatus himself and to receive feedback from the apparatus as to how to position the eye for proper administration of the liquid. Thus, the claimed subject matter provides features and advantages not known or available in the cited prior art. Consequently, the cited prior art will not support a rejection of claim 28 under 35 U.S.C. § 103 and *Graham*.

4. In the recent Office Action, claims 3, 18 and 19 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,945,650 to Beverly (hereinafter Beverly) in view of U.S. Patent Application Publication No. 2004/0267214 to Kerssies (hereinafter Kerssies) and in further view of U.S. Patent No. 6,270,467 to Yee (hereinafter Yee). The rejection of claims 3, 18, and 19 should be reconsidered and withdrawn for at least the same reasons given above in favor of the patentability of independent claim 1.

5. In the recent Office Action, claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,945,650 to Beverly (hereinafter Beverly) in view of U.S. Patent Application Publication No. 2004/0267214 to Kerssies (hereinafter Kerssies) and in further view of U.S. Patent No. 6,299,305 to Miwa (hereinafter Miwa). The rejection of claim 7 should be reconsidered and withdrawn for at least the same reasons given above in favor of the patentability of independent claim 1.

6. In the recent Office Action, claims 10, 14 and 15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,945,650 to Beverly (hereinafter Beverly) in view of U.S. Patent Application Publication No. 2004/0267214 to Kerssies (hereinafter Kerssies) and in further view of U.S. Patent No. 5,171,306 to Vo (hereinafter Vo). The rejection of claims 10, 14 and 15 should be reconsidered and withdrawn for at least the same reasons given above in favor of the patentability of independent claim 1.

7. In the recent Office Action, claims 11-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,945,650 to Beverly (hereinafter Beverly) in view of U.S. Patent Application Publication No. 2004/0267214 to Kerssies (hereinafter Kerssies) and

in further view of U.S. Patent No. 5,171,306 to Vo (hereinafter Vo) and U.S. Patent No. 5,368,582 to Bertera (hereinafter Bertera). The rejection of claims 11-13 should be reconsidered and withdrawn for at least the same reasons given above in favor of the patentability of independent claim 1.

8. In the recent Office Action, claims 17 and 32 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,945,650 to Beverly (hereinafter Beverly) in view of U.S. Patent Application Publication No. 2004/0267214 to Kerssies (hereinafter Kerssies) and in further view of U.S. Patent No. 5,368,582 to Bertera (hereinafter Bertera). The rejection of claim 17 and 32 should be reconsidered and withdrawn for at least the same reasons given above in favor of the patentability of independent claims 1 and 28.

9. In the recent Office Action, claim 22 was rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,945,650 to Beverly (hereinafter Beverly) in view of U.S. Patent No. 5,171,306 to Vo (hereinafter Vo). The rejection of claim 22 should be reconsidered and withdrawn for at least the same reasons given above in favor of the patentability of independent claim 20.

10. In the recent Office Action, claims 24, 25, and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,945,650 to Beverly (hereinafter Beverly) in view of U.S. Patent No. 6,159,186 to Wickham et al. (hereinafter Wickham). The rejection of claims 24, 25 and 29 should be reconsidered and withdrawn for at least the same reasons given above in favor of the patentability of independent claims 20 and 28.

11. In the recent Office Action, claims 26 and 27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,945,650 to Beverly (hereinafter Beverly) in view of U.S. Patent No. 6,159,186 to Wickham et al. (hereinafter Wickham) and in further view of U.S. Patent No. 5,171,306 to Vo (hereinafter Vo). The rejection of claims 26 and 27 should be reconsidered and withdrawn for at least the same reasons given above in favor of the patentability of independent claim 20.

Conclusion:

In view of the preceding arguments, all claims are believed to be in condition for allowance over the prior art of record. Therefore, this response is believed to be a complete response to the Office Action. However, Applicant reserves the right to set forth further arguments in future papers supporting the patentability of any of the claims, including the separate patentability of the dependent claims not explicitly addressed herein. In addition, because the arguments made above may not be exhaustive, there may be reasons for patentability of any or all pending claims (or other claims) that have not been expressed.

The absence of a reply to a specific rejection, issue, or comment in the Office Action does not signify agreement with or concession of that rejection, issue or comment. Finally, nothing in this paper should be construed as an intent to concede any issue with regard to any claim, except as specifically stated in this paper, and the amendment of any claim does not necessarily signify concession of unpatentability of the claim prior to its amendment. Further, for any instances in which the Examiner took Official Notice in the Office Action, Applicants expressly do not acquiesce to the taking of Official Notice, and respectfully request that the Examiner provide an affidavit to support the Official Notice taken in the next Office Action, as required by 37 CFR 1.104(d)(2) and MPEP § 2144.03.

If the Examiner has any comments or suggestions which could place this application in better form, the Examiner is requested to telephone the undersigned attorney at the number listed below.

Respectfully submitted,

DATE: August 11, 2010

/Steven L. Nichols/
Steven L. Nichols
Registration No. 40,326

STEVEN L. NICHOLS
Director, Intellectual Property Practice Group
VANCOTT PC
36 SOUTH STATE STREET, SUITE 1900
SALT LAKE CITY, UT 84111
P 801.237.0251
M 801.414.0750
F 801.237.0853
E snichols@vancott.com